

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)	Examiner: Sweet, Thomas
)	
Edward Knowlton)	Art Unit: 3774
)	
Application No. 10/813,980)	Confirmation No. 5920
)	
Filing Date: March 31, 2004)	Attorney Docket No. KNW-0018.US
)	
For: METHOD FOR TREATMENT OF)	
TISSUE)	Customer No. 77845
)	

DECLARATION OF EDWARD W. KNOWLTON, M.D. UNDER 37 C.F.R.
§ 1.132

Sir:

I, Edward W. Knowlton, M.D. declare and say as follows:

1. I am the inventor of the above-identified patent application.
2. I am an active Plastic Surgeon with 26 years of experience in private practice. I graduated from the Washington University Medical School in St. Louis in 1973, completed my surgical residency in 1978, and was certified by the American Board of Plastic Surgery in 1981. I have authored numerous patents in the medical device field and have written several scientific papers on Plastic Surgery including an innovative approach to breast reconstruction called the Peg Procedures. I have founded the Danville Ambulatory Surgery Center, an outpatient Plastic Surgery Center of Excellence that was established in 1983, and am the original founder of the Thermage Corporation.
3. My scientific Curriculum Vitae is attached to and forms part of this Declaration.
4. I am familiar with the tissue remodeling apparatus and the methods of its use as disclosed in US Patent 6,350,276. This apparatus has been used by me and others under my supervision, to modify skin surfaces and underlying tissue via the delivery of energy and fluid.
5. The object of the invention described in US Patent 6,350,276 was to provide a method and apparatus that delivered a mechanical force and electromagnetic energy to a tissue

site to change a skin surface and/or change the contour of a soft tissue structure. The apparatus included a template with a skin interface surface that was used to conform the tissue using mechanical compression.

6. It is my opinion that the method and apparatus disclosed in US Patent 6,350,276, using a conforming template combined with mechanical compression, does not adequately secure the repositioned skin in place or sufficiently produce a desired amount of tissue remodeling.

7. By contrast, the invention of the instant application provides for the creation of directed thermal lesions for a desired therapeutic effect. Specifically, the instant application takes into consideration the vectored pre-positioning of the tissue. In one embodiment, vectored pre-positioning of the selected tissues can be used to shape the thermal lesion so as to create or facilitate the creation of a directed wound healing response. To this end, a number of surgical techniques can be employed, including but not limited to, pre-positioning the selected tissue by hand, suturing the tissue in place, using a steri strip, using a surgical/tissue adhesive, or using a surgical clamping device known in the art. Hence, the claimed methods of the instant application constitute a novel advancement in the field of tissue remodeling and one skilled in the art would not agree that the instant application is anticipated or made obvious by the disclosure in US Patent 6,350,276.

8. I declare further that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further, that these statements are made with the knowledge that willful statements and the like so made are punishable by fine or imprisonment, or both,' under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent granted thereon.

Signed: Edward W. Knowlton M.D.

Date: 12/13/08

Edward W. Knowlton, M.D.